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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
BLANCHARD, DAVID J	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 02/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/967,237	ZAVADA ET AL.	
	Examiner	Art Unit	
	David J Blanchard	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 July 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22,23 and 30-51* is/are pending in the application.

4a) Of the above claim(s) *24-27, 32-35, 39-4144-45 and 49-51* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-23, 30-31, 36-38, 42-43 and 46-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-21, 28-29 and 52 have been cancelled.

Claims 22-23, 30-31, 37, 42 and 47-48 have been amended.

Claims 24-27, 32-35, 39-41, 44-45 and 49-51 remain withdrawn from consideration as being drawn to a nonelected invention.

2. Claims 22-23, 30-31, 36-38, 42-43 and 46-48 are under examination.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. This Office Action contains New Grounds of Rejections.

Objections/Rejections Withdrawn

5. The objection to the specification for various informalities are withdrawn in view the amendments to the specification.

6. The objection to the title as not descriptive of the claimed invention is withdrawn in view of the amended title.

7. The rejections of claims 22-23, 30-31, 36-38, 42-43 and 46-48, parts a-c, under 35 U.S.C. 112, second paragraph, as being as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention are withdrawn in view of applicant's arguments and amendment to the claims.

8. The rejection of claims 30-31, 36-38, 42-43, 46-48 and 52 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in view of applicant's arguments.

9. The rejection of claims 23 and 31 under 35 U.S.C. 112, first paragraph because the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention, because the specification does not provide evidence that the claimed biological materials are (1) known and readily available to the public and (2) reproducible from the written description is withdrawn in view of the successful completion of the deposit requirements.

Response to Arguments

10. The rejection of claims 22, 30, 36-38, 42-43 and 46-48 under 35 U.S.C. 112, first paragraph because the specification does not enable any person skilled in the relevant art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with the claims is maintained in part.

The response filed 7/27/2004 has been carefully considered but is deemed not to be persuasive. The response argues numerous different points with respect to the outstanding enablement rejection. In view of theses arguments and the claims as currently amended, while being enabling for anti-idiotypic antibodies to an idiotype of a second antibody that specifically binds to an epitope of the native MN protein, wherein the MN protein is encoded by SEQ ID NO:1 or polynucleotides that differ from SEQ ID NO:1 due to the degeneracy of the genetic code, does not reasonably provide enablement for anti-idiotypic antibodies to an idiotype of a second antibody that specifically binds fragments of MN proteins or the MN protein encoded by a polynucelotides that differ from SEQ ID NO:1 or polynucleotides that hybridize under the

recited conditions to SEQ ID NO:1's complement or differ from these hybridizing polynucleotides due to the degeneracy of the genetic code as defined by the claims. The claims still encompass anti-idiotypic antibodies to an antibody that binds to fragments of the MN protein, which anti-idiotypic antibodies would not express three-dimensional shapes that resemble the structure of the natural MN antigen. As evidenced by the art of Raychaudhuri, Wu, and Chatterjee (cited by the examiner in the previous Office Action) it is reiterated that only Ab2 betas, which bind to the CDRs can be an internal image of the antigen and are proposed to be paratropic and mimic the molecular features of the original antigen. Chatterjee states "Some of these Ab2 molecules can effectively mimic the three-dimensional structure of the tumor-associated antigen identified by the Ab1" (i.e., the monoclonal antibody).

Applicant appears to have acknowledged this and admits at pages 13-14 of the response, which states,

> "Uemura et al...define an anti-idiotype antibody (Ab2) as "an antibody directed against an antigenic determinant located within a variable region of the immunoglobulin molecule. Ab2 mimicking the normal antigen (so-called internal image Ab2) may be used as a surrogate antigen for vaccination to trigger the host's immune system specifically against the normal antigen."

Applicant as well as the art recognizes that the antigen mimicry properties of anti-idiotypic antibodies depend upon its three-dimensional conformation that resembles the structure of the natural antigen (MN protein in this case). Applicant admits at page 8 of the response stating "One of skill in the art would see that inherent in the statement at column 25, lines 1-3 of Zavada et al, '676 patent is the necessity that the anti-idiotype antibodies to antibodies to MN proteins/polypeptides must mimic MN

proteins/polypeptides to be useful, as MN proteins/polypeptides would be, when formulated in a vaccine." Applicant has not provided any objective evidence that the fragments of the MN protein as defined by the claims would mimic the structural properties of the natural MN protein expressed on the surface of neoplastic cells or antibodies that bind these MN fragments would produce anti-idiotypes that are an internal image and mimic the three-dimensional properties of the natural MN protein since in applicant's own words the "anti-idiotype antibodies to antibodies to MN proteins/polypeptides must mimic MN proteins/polypeptides to be useful, as MN proteins/polypeptides would be, when formulated in a vaccine." One of skill in the art would not expect nor predict the appropriate functioning of the anti-idiotypic antibodies as broadly defined by the claims.

Applicant argues that the burden of proof to challenge the presumptively enabling disclosure of the instant application has not been met concerning the claimed anti-idiotypic antibodies to an antibody that MN polypeptide and applicant cites MPEP 2164.04 stating that statements in a patent application specification relied upon for enabling support that correspond in scope with the claimed invention "must be taken as in compliance with the enabling requirement of the first paragraph of paragraph 112 unless there is reason to doubt the objective truth of" those statements. In response to this argument and as discussed above, the evidence provided in applicant's own specification and reiterated in applicant's response as well as the art cited by the examiner clearly establish a factual basis upon which to make the instant enablement rejection. As above, the antigen mimicry properties of anti-idiotypic antibodies depend

upon its three-dimensional conformation that resembles the structure of the natural antigen (MN protein in this case) and Applicant has not provided any objective evidence that the fragments of the MN protein as defined by the claims would mimic the structural properties of the natural MN protein expressed on the surface of neoplastic cells or antibodies that bind these MN fragments could be predictably used to produce anti-idiotypes that are an internal image and mimic the three-dimensional properties of the natural MN protein. Again, in applicant's own words the "anti-idiotype antibodies to antibodies to MN proteins/polypeptides must mimic MN proteins/polypeptides to be useful, as MN proteins/polypeptides would be, when formulated in a vaccine." While the examiner agrees that the specification is enabling for anti-idiotypic antibodies that bind to the idiotype of an antibody that binds the native MN protein, the specification does not enable anti-idiotypic antibodies that bind to the idiotype of an antibody that binds the myriad of MN fragments as defined by the claims.

The response at page 26-28 argues that polynucleotides that hybridize under stringent conditions to the complement of SEQ ID NO:1 are defined in compliance with the written description requirement of 35 U.S.C 112, first paragraph. In response, these arguments are not relevant to the instant rejection, which was made under 35 U.S.C. 112, first paragraph, enablement and not written description. Applicant is reminded that *Vas-Cath* (*Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111) makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115). With respect to the instant enablement rejection, applicant argues that the specification describes MN proteins and MN polynucleotides as substantially similar or

homologous to the amino acid sequence of SEQ ID NO:2 (i.e., the MN protein) and having similar epitopes. Applicant argues that the specification sets forth epitopes (i.e., SEQ ID Nos:10-16), two hybridomas that secrete Mabs M75 and MN12, which allow one of skill in the art to identify and isolate MN antigen and can be used in conventional screens to identify MN protein/polypeptides. Further applicant states that the identification of epitopes, conventional screening protocols can be used to determine if a protein or polypeptide encoded by a nucleotide sequence of 29 or more nucleotides that hybridizes to SEQ ID NO:1 under stringent hybridization conditions (i.e., 50% formamide at 42°C) has epitopes recognized by antibodies that bind specifically to known MN protein/polypeptide, as that having the sequence of SEQ ID NO:2 or other naturally occurring MN protein/polypeptide. At page 29, the response continues by stating that one of skill in the art could use a commercially available computer program such as PCGENE™ to identify MN epitopes when given SEQ ID NO:2 and the specification at page 74 describes the use of a commercially available kit - Novatope® system which is useful for epitope mapping. In response to these arguments, it is pointed out that applicant claims are drawn to (c) polynucleotides that differ from SEQ ID NO:1 (i.e., any polynucleotide sequence), and polynucleotides that differ from the polynuceotides that hybridize under the recited stringent conditions due to the degeneracy of the genetic code as well as (b) polynucleotides that hybridize under the recited stringent conditions to SEQ ID NO:1's complement, which according to applicant at page 34 encompasses nucleotide sequence that have 80-90% homology to SEQ ID NO:1. According to the specification at page 2, lines 1-2, "The MN protein is now

considered to be the first tumor-associated carbonic anhydrase (CA) isoenzyme that has been described." Applicant has not provided any objective evidence of any other carbonic anhydrase isoenzyme that is tumor-associated and would be useful as a therapeutic composition (i.e., as an anti-idiotypic antibody). The specification does not disclose any polynuceotide that encodes a polypeptide having an epitope that is similar to an epitope of SEQ ID NO:2 (the MN protein), what this epitope actually is or any polynucleotide that encodes an MN protein, not the MN protein (i.e., SEQ ID NO:2) as broadly encompassed by the claims. According to applicant's arguments that the specification teaches methods for identifying polynucleotides that are similar to SEQ ID NO:1, which in essence, the specification simply directs those of skill in the art to go figure out for themselves how to use the polynucleotides and the encoded polypeptides as a starting point for the production and use of anti-idotypic antibodies as a therapeutic composition in the treatment of cancer, which without more precise guidelines, amount to little more than "a starting point, a direction for further research." *Genentech*, 108 F.3d at 1366. *See also Calgene*, 188 F.3d at 1374 ("the teachings set forth in the specification provide no more than a 'plan' or 'invitation' for those of skill in the art to experiment practicing [the claimed invention]; they do not provide sufficient guidance or specificity as to how to execute that plan"); *National Recovery Technologies*, 166 F.3d at 1198 (stating that patent-in-suit "recognizes a specific need... and suggests a theoretical answer to that need. It provides a starting point from which one of skill in the art can perform further research in order to practice the claimed invention, but this is not adequate to constitute enablement"). The instant specification does not describe the

claimed invention in terms that will "enable any person skilled in the art... to make and use" the invention commensurate in scope with the claims. At most, the specification will enable a person of ordinary skill in the art to attempt to discover how to practice the claimed invention. In view of the statement in applicant's own specification that the MN protein (i.e., SEQ ID NO:2) is the first tumor-associated carbonic anhydrase described and in view of the absence of objective evidence of other carbonic anhydrases similar to the MN protein that are also tumor-associated and thus, useful as therapeutic compositions (i.e., as an anti-idiotype) and without more specific guidance and direction as to how one of skill in the art would find such sequences as well as identify a correlation of the identified 'similar sequence' to tumors, one of ordinary skill in the art would be forced into undue experimentation.

Applicant also argues that as pioneers of MN as well as MN's diagnostic, prognostic and therapeutic uses, applicant is entitled to claim broadly and for support applicant cites In re Hogan and Banks. Applicant argues that if the instant claims are limited to the sequence of the MN protein (i.e., SEQ ID NO:2), anyone could avoid infringement of such a claim by slightly modifying the sequence. As applicant asserts an unduly narrow claim limited to SEQ ID NO:2 would require that applicant's dedicate their invention to the public. With respect to the instant claims as being drawn to an MN protein encoded by SEQ ID NO:1 and sequences that hybridize to the complement of SEQ ID NO:1 under the recited conditions and sequences that differ from SEQ ID NO:1 by the degeneracy of the genetic code, it is pointed out that applicant is enabled for the MN protein encoded by SEQ ID NO:1 as well as MN proteins encoded by

polynucleotides that differ from SEQ ID NO:1 due to the degeneracy of the genetic code. Thus, the claims are not merely limited to SEQ ID NO:1 and the encoded polypeptide of SQE ID NO:2. With respect to the instant claims drawn to fragments of the MN protein, as encompassed by the claim language, i.e., encoded by polynucleotides at least 29, 50, 100, 150, 25 and 27 nucleotides as well as a fragment of SEQ ID NO:1 and a nucleic acid that has a nucleotide sequence from SEQ ID NO:1 do not meet the enablement requirement under the first paragraph of 35 U.S.C. as discussed above. The examiner can appreciate applicant's pioneering invention, however, applicant must provide sufficient guidance and direction to assist one of skill in the art to predictably practice the claimed invention with a reasonable expectation of success, commensurate in scope with the claims.

Priority

Czechoslovakian Patent application PV-709-92 discloses the M75 monoclonal antibody secreted from the hybridoma VU-M75. This does not provide adequate descriptive support for the instantly claimed invention, which is drawn to anti-idiotypic antibodies that mimic the MN protein. In view of applicant's arguments showing that the MN cDNA and amino acid sequence of the '676 patent are the same as that disclosed in the instant application, the filing date of the instant claims is deemed to be the filing date of parent application USSN 07/964,589, i.e., 10/21/1992 (now U.S. Patent 5,387,676).

11. The rejection of claims 22-23, 30-31, 36-38, 42-43 and 46-48 under 35 U.S.C. 103(a) as being unpatentable over Pastorekova et al as evidenced by Pastorek et al in view of Raychaudhuri et al is maintained.

The response filed 7/27/2004 has been carefully considered, but is deemed not to be persuasive. The response argues that Pastorekova et al is not prior art as applicant is entitled to the effective filing date of the Czechoslovakian priority application filed 3/11/1992, which is before the publication date of Pastorekova et al. In response to this argument and as discussed above under 'Priority', the Czechoslovakian patent application does not provide adequate written description for anti-idiotypic antibodies and thus, does not support the instantly claimed invention. Therefore, the effective filing date of the instant claims is deemed to be that of USSN07/964,589 (now U.S. Patent 5,387,676) filed 10/21/1992. The examiner acknowledges that the publication date of the Pastorekova et al is April 1992, however, this date is still clearly before the filing date of USSN 07/964,589, 10/21/1992.

The response also argues that Pastorekova et al does not enable the claimed invention. Applicant is reminded that when a reference relied on anticipates or makes obvious all of the elements of the claimed invention, the references presumed to be operable. Once such a reference is found, the burden is on applicant to provide facts rebutting the presumption of operability (MPEP 2121). Applicant's arguments are not persuasive in the absence of objective evidence providing a factual basis that the monoclonal antibody M75 was not publicly available. Applicant's arguments with respect to the isolation and characterization of the MN antigen are simply not relevant

as the instant claims are drawn to an anti-idiotypic antibody and characterization or even identification of the antigen is not required. The monoclonal antibody M75 is in the prior art, and it was known that M75 binds an antigen that is part of a human tumor antigen (i.e., part of MaTu) and it was known in the art that tumor antigens are weakly immunogenic and that this deficiency could be overcome with anti-idiotypic antibodies of the beta type that are an internal images of the tumor antigen and effectively induce tumor immunity when administered as a therapeutic agent as taught by Raychaudhuri et al. The strongest rationale for combining reference is a recognition, expressly or implicitly in the prior art or drawn from a convincing line of reasoning based on established scientific principles or legal precedent that some advantage or expected beneficial result would have been produced by their combination In re Sernaker 17 USPQ 1, 5-6 (Fed. Cir. 1983) see MPEP 2144

Furthermore, Applicant admits at page 19 of the response that Raychaudhuri, the '202 patent, and a number of references cited in the '202 patent provide evidence of the conventionality in the art of making and using anti-idiotypic antibodies well before the earliest priority date for the instantly claimed MN-specific anti-idiotypic antibodies. Therefore, for the reasons of record in the previous Office Action reiterated herein and in view of the admission by applicant that it is well know and conventional in the art to make and use anti-idiotypic antibodies, it would have bee prima facie obvious to one of ordinary skill in the art at the time the invention was made to have produced anti-idiotypic antibodies to Mab M75 taught by Pastorekova et al in order to produce an

internal image of the human tumor antigen recognized by Mab M75 for therapeutic benefit of human tumors.

Further, in response to applicant's arguments against the references individually, one cannot show non-obviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references and the rejection is maintained.

12. The rejection of claims 22, 30, 36-38, 42-43 and 46-48 under 35 U.S.C. 103(a) as being unpatentable over Oosterwijk et al [a] (WO 88/08854) as evidenced by Uemura et al and as evidenced by Pastorek et al in view of Raychaudhuri et al is maintained.

The response filed 7/27/2004 has been carefully considered, but is deemed not to be persuasive. The response argues the references individually stating that Pastorek et al and Uemura et al are published after the priority date of the instant application and thus, are not prior art. In response, Pastorek et al and Uemura et al were cited as evidence to show an inherent property that is necessarily present in the prior art of Oosterwijk [a], that is, the G250 antigen is identical to the MN protein and as such monoclonal antibody G250 (Mab G250) taught by Oosterwijk et al [a] would necessarily

bind to the MN protein. Applicant is reminded that products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01. The response argues that the Oosterwijk et al [a] reference does not provide an enabling disclosure of the G250 antigen and provides incorrect indications concerning the identity of the G250 antigen and one of skill in the art would not associate the G250 antigen with the MN protein. The response continues by arguing that the Oosterwijk et al [a] reference cannot render obvious the instant claims since the G250 antigen is, not only not identified by any chemical characteristics, but the immunoreactivity of Mab G250 is very different from the actual characterization of the MN protein disclosed in the instant application. In response, these arguments are not relevant to the instant rejection because it is Mab G250 taught by Oosterwijk et al [a] that is the relevant antigen for the production of an anti-idiotypic antibody. Characterization and identification of the G250 antigen and its association with the MN protein are not required for the production of an anti-idiotypic antibody and thus, are simply not relevant. It is reiterated that Oosterwijk et al [a] teach that Mab G250 that binds a renal cell carcinoma antigen, the G250 antigen, which antibody would necessarily bind the MN protein as evidenced by Uemura et al and Pastorek et al and Raychaudhuri et al teach that immunization with anti-idiotypic antibodies of the beta type, bearing the internal image of a tumor antigen, induces tumor-specific immunity and can inhibit tumor growth. Thus, it would have

been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have produced an anti-idiotype antibody to Mab G250 as a therapeutic composition for treating renal cell carcinomas.

Furthermore, Applicant admits at page 19 of the response that Raychaudhuri, the '202 patent, and a number of references cited in the '202 patent provide evidence of the conventionality in the art of making and using anti-idiotypic antibodies well before the earliest priority date for the instantly claimed MN-specific anti-idiotypic antibodies. Therefore, for the reasons of record in the previous Office Action and reiterated herein and in view of the admission by applicant that it is conventional in the art to make and use anti-idioptypic antibodies, it would have bee prima facie obvious to one of ordinary skill in the art at the time the invention was made to have produced anti-idiotypic antibodies to Mab G250 in order to produce an internal image of the renal cell carcinoma antigen recognized by Mab G250 for therapeutic benefit of renal cell carcinomas.

Further, in response to applicant's arguments against the references individually, one cannot show non-obviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references and the rejection is maintained.

13. The rejection of claims 22, 30, 36-38, 42-43 and 46-48 under 35 U.S.C. 103(a) as being unpatentable over Oosterwijk et al [b] (International Journal of Cancer 38:489-494, 1986, Ids 10/19/01) as evidenced by Uemura et al and as evidenced by Pastorek et al in view of Raychaudhuri et al is maintained.

The response filed 7/27/2004 has been carefully considered, but is deemed not to be persuasive. The response argues as above and the rebuttal to these arguments is as above (see item #13).

Conclusion

14. No claim is allowed.

15. Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Blanchard whose telephone number is (571) 272-0827. The examiner can normally be reached at Monday through Friday from 8:00 AM to 6:00 PM, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at (571) 272-0787. The official fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,
David J. Blanchard
571-272-0827

LARRY R. HELMS, PH.D
PRIMARY EXAMINER

LARRY R. HELMS, PH.D
PRIMARY EXAMINER